Arthritis & Rheumatism (Arthritis Care & Research)
Vol. 51, No. 2, April 15, 2004, pp 184–192
DOI 10.1002/art.20252

ORIGINAL ARTICLE

Long-Term Efficacy of Therapy in Patients With Fibromyalgia: A Physical Exercise-Based Program and a Cognitive-Behavioral Approach

JAVIER RIVERA REDONDO,[1] CARMEN MORATALLA JUSTO,[1] FRANCISCA VALDEPEÑAS MORALEDA,[1] YOLANDA GARCÍA VELAYOS,[2] JOSÉ JUAN OSÉS PUCHE,[1] JULIO RUIZ ZUBERO,[1] TERESA GONZÁLEZ HERNÁNDEZ,[1] LORETO CARMONA ORTELLS,[3] AND MIGUEL ÁNGEL VALLEJO PAREJA[2]

Objective. **To analyze the long-term efficacy of 2 interventions for female fibromyalgia (FM) patients: 1) cognitive-behavioral therapy (CBT), and 2) a physical exercise (PE)–based strategy.**

Methods. **We conducted a prospective, long-term, randomized, parallel clinical trial. The outcome variables are physical activity, aerobic capacity, and results of the Fibromyalgia Impact Questionnaire (FIQ), Short Form 36, Beck Anxiety and Depression Inventory, Chronic Pain Self-Efficacy Scale, and Chronic Pain Coping Inventory. All were measured at baseline, posttreatment, 6 months, and 1 year. The duration of both treatments was 8 weeks.**

Results. **Some items of the FIQ and some strategies to cope with pain improved significantly in both groups after treatment. All variables measuring functional capacity improved significantly in the PE group, whereas only physical activity of the vertebral column improved in the CBT group. There were no differences in anxiety, depression, and self efficacy after treatment in either group. After 1 year of followup, most of the parameters had returned to baseline values in both groups. However, in the PE group, functional capacity remained significantly better.**

Conclusions. **PE and CBT improve clinical manifestations in FM patients only for short periods of time. Improvement in self efficacy and physical fitness are not associated with improvement in clinical manifestations.**

KEY WORDS. Fibromyalgia; Pain treatment; Exercise treatment; Cognitive-behavioral therapy; Physical fitness

INTRODUCTION

Fibromyalgia (FM) is a complex clinical syndrome characterized by chronic widespread musculoskeletal pain, sleep disturbances, morning stiffness, fatigue, anxiety, and depressive symptoms. Its etiology is not known, and several aspects of its pathogenesis are being investigated, shedding some light on the possible physiopathologic mechanisms involved in this process.

[1]Javier Rivera Redondo, MD, Carmen Moratalla Justo, Francisca Valdepeñas Moraleda, José Juan Osés Puche, MD, Julio Ruiz Zubero, MD, Teresa González Hernández, MD: Instituto Provincial de Rehabilitación, Hospital Universitario Gregorio Marañón, Madrid, Spain; [2]Yolanda García Velayos, Miguel Ángel Vallejo Pareja, PhD: Universidad Nacional de Educación a Distancia (UNED), Madrid, Spain; [3]Loreto Carmona Ortells, MD: (current address: Hospital Clínico Universitario San Carlos, Madrid, Spain) Unidad de Investigación Sociedad Española de Reumatología.

Address correspondence to Javier Rivera Redondo, MD, Ábrego 19, 1D, Pozuelo de Alarcón 28223 Madrid, Spain. E-mail: javierrivera@ser.es.

Submitted for publication July 19, 2002; accepted in revised form June 25, 2003.

It has been hypothesized that FM is a disease of the mechanisms related to pain processing both at a central level (1) and at the peripheral level (2). This would result in a generalized situation of hyperalgesia. Several neurohormonal alterations have been described in these patients that could justify the pain and explain part of this hypothesis (3).

The presence of widespread pain in muscular areas, muscular weakness, fatigue, and stiffness reported by these patients suggests that there could exist an underlying muscle pathology, or at least a pathogenic mechanism in which muscles play an important role. Indeed, morphologic and functional studies carried out on muscles and tender points have shown a series of structural biochemical and functional alterations, which are not exclusive to FM and can be observed in other processes (4).

One of the most commonly observed functional alterations in these patients is their poor physical fitness, characterized by a lesser capacity to perform physical exercise and an increasing tendency to fatigue on usual activities (5). What remains to be determined is whether this poor physical fitness is produced by the lack of physical activity

observed in these patients or whether it is resulting from an illness of the musculoskeletal system. In any case, it has been shown that both aerobic capacity and muscular strength can improve after programs of physical training without any harm to the patient (6,7).

In FM treatment, analgesics, antiinflammatory drugs, muscle relaxants, and antidepressants have been used. Most clinical trials with drugs, although useful to improve clinical symptoms in these patients, have been carried out for short periods of time (8). Because FM is a problem of chronic pain, the results of any treatment should be evaluated in the long term. There are no followup studies of drug treatments that allow us to value their usefulness for extended periods of time. On the other hand, the followup studies of patients with FM show that patients very often abandon medication because the symptoms do not change despite long-term treatment (9,10).

Recently, several nonpharmacologic treatments have been tried in patients with FM. In fact, since the seminal work of McCain et al (11), which showed an improvement in the symptoms of the FM patients treated with physical exercise (PE), several clinical trials have been published confirming the beneficial effects of several types of PE-based treatments (12–17). However, followup studies in these patients have shown that clinical benefits do not persist (13). One possible explanation of these findings may be the loss of physical fitness, which precludes drawing conclusions about the long-term effect of good physical fitness in clinical manifestations of FM patients.

Treatments with learning techniques designed to improve several cognitive and behavioral aspects of the internal control of reactivity in situations of chronic pain (cognitive-behavioral therapy [CBT]) have proved useful in the treatment of FM (13,18) and other rheumatic diseases (19,20). Although the need for focusing on the maintenance of treatment gains generated by CBT interventions has been previously described in rheumatoid arthritis patients (20), most of the clinical trials in FM patients have only been carried out during short periods of time and the final evaluation of the results has been performed immediately after finishing the treatment.

In the short term, treating FM with only CBT has proved less efficient than treating with PE (21). However, treatments that combine several types of CBT and PE have achieved better results (18,22–25). The goal of this article is to analyze the long-term efficacy of 1 type of CBT and of a PE-based strategy in patients with FM.

PATIENTS AND METHODS

Patients. All patients in this study were referred by general practitioners at the Rheumatology Unit of a tertiary care teaching hospital for study and treatment of chronic widespread musculoeskeletal pain. Fifty-six consecutive female patients, who fulfilled the American College of Rheumatology (ACR) criteria for the diagnosis of FM (26), were informed about the objective and methodology of the study and were invited to participate in the trial. Patients with serious concomitant disease were excluded.

All patients completed clinical and psychological questionnaires upon entry and underwent a physical exam including cardiovascular fitness to assess their capacity to perform the exercise program. Demographic variables were also collected at baseline.

Study design and procedures. This is a prospective, long-term, randomized, parallel trial that analyzes the efficacy of PE-based therapy and CBT in the treatment of patients with FM. After obtaining written informed consent, patients were randomized by means of a random numbers table to either a group of PE and aerobic fitness (PE group) or to a group of CBT (CBT group).

All patients underwent 4 evaluations: a baseline assessment, another at the end of the 8-week treatment program (posttreatment assessment), another 6 months after the end of the program, and a final evaluation 1 year after completing the treatment program. Physicians that assessed physical activity and aerobic exercise capacity were blinded with respect to the group of therapy to which patients belonged. The PE program was administered by physiotherapists and testing of outcome measures was performed by physicians. The CBT program and testing were performed by the same psychologists.

Clinical and psychological self questionnaires were administered in all evaluations, and functional capacity and aerobic exercise capacity were also measured. Information about daily drug consumption and PE activities were collected as well.

After the first visit, all patients were offered pharmacologic treatment with antiinflammatory doses of ibuprofen or diclofenac, amitryptiline at a dose of 25 mg at night, and acetaminophen on a time-contingent basis. The assessment of drug therapy was not an objective of this trial and patients were left free to modify medication on the basis of their clinical response.

This clinical trial was approved by the ethical committee of Hospital Universitario Gregorio Marañón, Madrid.

Outcome measures. *The tender point score.* Tender points were explored by digital palpation at 18 sites, following ACR recommendations (26). The range of the score lies between 0 and 18.

The Fibromyalgia Impact Questionnaire (FIQ). The FIQ is a self-administered questionnaire developed and validated for its use in patients with FM (27). It measures physical functioning, work status, and overall well being; it also contains 6 visual analog scales (VASs) for pain, sleep, fatigue, morning stiffness, anxiety, and depression. A total score may be obtained after normalization of some items and summing with all VASs. The range of the total score is between 0 and 80 (without job-related items), where a higher score indicates a negative impact. The FIQ has shown to be the most responsive measure to perceive clinical improvement in patients with FM (28).

The Short Form 36 (SF-36). The SF-36 is a self-administered questionnaire for measuring quality of life through the perception of health by the patient (29). In this study we used the Spanish version of SF-36, which has been validated in our population (30). It contains 36 items grouped into 8 subscales: physical functioning, physical

role, bodily pain, general health, vitality, social functioning, emotional role, and mental health. The range of scores is between 0 and 100 in every subscale, where higher scores indicate better health. The SF-36 does not obtain a global score. One item in this questionnaire measures health change during the past year in a Likert-like scale in which 1 = "much better," 2 = "better," 3 = "unchanged," 4 = "worse," and 5 = "much worse."

The Beck Anxiety Inventory. This instrument measures anxiety severity while discriminating anxiety from depression. It contains 21 items with a total score of 0–63, where higher scores indicate more anxiety (31).

The Beck Depression Inventory. This is a questionnaire developed and validated for patients with depression. It contains 21 items that assess the cognitive, affective, and neurovegetative factors associated with depression. The range of score is 0–63, where values above 13 indicate presence of depression, and values above 21 indicate major depression (32).

The Chronic Pain Self-Efficacy Scale (CPSS). The CPSS is a modified version of The Arthritis Self-Efficacy Scale (33) that has been developed and validated for patients with chronic pain (34). It contains 22 items grouped into 3 subscales: self efficacy for pain management, self efficacy for coping with symptoms, and self efficacy for physical function. The scores are obtained by means of a Likert scale with a range of 0–10, where higher scores indicate better self efficacy.

The Chronic Pain Coping Inventory. This is a questionnaire that measures the strategies used by patients to cope with chronic pain (35). It contains 65 items assessing 8 pain coping dimensions: asking for assistance, guarding, resting, relaxation, task persistence, exercise, social support, and self statements. Each dimension is scored by the number of days during the past week that the patient used specific strategies to cope with pain.

Physical activity of vertebral column and upper and lower limbs. Three bodily areas were explored: upper limbs (shoulders), lower limbs (hips and knees), and dorsolumbar spine. At each area, joint mobility, pain with movement, and muscular endurance were assessed.

Mobility was assessed by the range of all movements of a joint. The maximum range of movement was scored as 10, subtracting 2 points for each 25% decrease in the range of movement. If a joint was shown to have <25% of its maximum range of motion, it was given a score of 2. An average of all joint movement scores was calculated, with the total range of 2–10 in each bodily area.

Pain with movement was assessed on a 5-point Likert scale where 10 = "no pain," 8 = "minimal pain," 6 = "moderate pain," 4 = "severe pain," and 2 = "pain does not permit the movement." An average pain score was obtained from all joint movements, with a range of 2–10 in each bodily area.

Muscle endurance in the upper limbs was measured by the number of shoulder abductions performed with a 1-kg weight in the hand. In the lower limbs, endurance was assessed with the number of knee extension with a 2-kg weight and by the number of body weight lifts over 1 foot. In the dorsolumbar spine, endurance was assessed by the number of ventral flexions and dorsal extensions performed by the patient lying down in a resting position. Twenty or more of these movements are scored as 10, and for every 5-movements decrease, 2 points were subtracted of the maximum score. An average of all scores was obtained, with the total range of muscular endurance between 2 and 10 in each bodily area.

To obtain a final punctuation, scores in mobility, pain, and muscle endurance were summed, yielding a final score ranging from 6 to 30 in each bodily area, where higher scores indicate a better physical activity.

Measure of aerobic exercise capacity. Using a cycle ergometer, by means of an incremental exercise test, the work rate was increased uniformly in magnitude and duration following the Bruce protocol (36). V_{O_2} (oxygen consumption) was estimated in relation to performed work rate, assuming there exists a relationship between these 2 variables. The estimated V_{O_2} is divided by 3.5 to obtain the number of metabolic rates (METs) performed by the individual while doing exercises. One MET is defined as the energy expenditure for an average adult sitting quietly (37), which is ~3.5 ml/minute/kg of body weight. The test is finished by volitional exhaustion or when the patient reaches maximum hearth rate. This same measure of aerobic exercise capacity has been used by other investigators (13,16,38).

Description of the PE and cardiovascular fitness program. This program consisted of a 45-minute session of PE 5 times weekly. PE in this protocol was designed to enhance cardiovascular fitness, muscular endurance, and flexibility. Each session included a preliminary warm-up exercise followed by the specific objective proposed in that session. Each week there was 1 session of exercises in a warm-water pool, 2 sessions of flexibility and endurance exercises, and 2 sessions of cardiovascular fitness by means of a cycle ergometer and isokinetic exercises with weights for upper limbs. This program lasted 8 consecutive weeks, with steeply increasing difficulty of exercises. At the end of the 8-week program, all patients in this group were instructed to maintain daily physical exercises at home.

A similar PE and cardiovascular fitness program has demonstrated to produce positive results in previous studies (11,16,17,38,39).

Description of the CBT program. This program lasted 8 consecutive weeks with a once-weekly session of 2.5 hours. CBT was mainly designed for reducing distorted pain dimensions, to cope with chronic pain, and to increase self efficacy, following techniques previously described for the management of chronic pain (40).

The following information and specific behavioral techniques were included: information about chronic pain and related emotional aspects, information about the nature of FM, learning relaxation techniques, learning to cope with chronic pain, learning to cope with daily living activities, social abilities, sleep and resting, problem solving, and prevention of relapses. Similar interventions have been previously used for treating FM (41) and other rheumatic diseases (19,20), with positive results.

Statistical analysis. Chi-square and Fisher exact tests were used to compare demographic and clinical categorical variables between both groups. To compare means, *t*-tests were used for independent variables, and paired *t*-tests were used for paired variables. The analysis of the data was calculated according to the principle of intention-to-treat for maintaining baseline variable conditions. A Bonferroni correction with alpha level of 0.01 was used for considering significant findings in multiple comparisons.

RESULTS

Of the 56 female patients initially evaluated for entry into the trial, 16 did not participate. Two patients showed poor cardiovascular fitness and were withdrawn. Two other patients without motor vehicle lived far from the hospital and they decided not participate in the study. Fourteen patients refused to participate by personal unspecified reasons. The remaining 40 patients were randomly assigned into groups, with 21 patients included in the CBT group and 19 patients in the PE group. After randomization, demographic characteristics, clinical symptoms, psychological measures, and physical function were similar, with no statistical differences between groups.

Five patients in the CBT group did not complete the trial. In 2 cases, there was no subjective improvement with the proposed treatment and they decided to drop out. One patient moved out of the city, and 2 other patients did not complete entire evaluations. In the PE group, 4 patients did not complete the trial. Two patients dropped out because of concomitant illnesses, 1 with pneumonia and the other with a coxofemoral limiting pain due to severe osteoarthritis. Two more patients did not complete entire evaluations. The number of patients who completed the trial was 31, 16 in the CBT group and 15 in the PE group.

The rate of compliance with sessions was similar in both groups (mean $\pm$ SD, PE group 84.1 $\pm$ 18.3% versus CBT group: 72.1 $\pm$ 24.2%; $P > 0.05$).

Intragroup differences. *PE group.* At the end of the completion of the 8-week treatment program, an improvement in some of the variables analyzed in this trial was found, compared with basal assessment (Table 1 and Figure 1). Most of the items and the total score of the FIQ improved significantly in these patients. In the SF-36 questionnaire, only the bodily pain domain showed a significant improvement. In relation to the strategies used by patients of this group to cope with chronic pain, the use of exercises was higher, showing an increased use of these strategies after the treatment. There were no statistical differences in anxiety, depression, and self-efficacy scales, measured by specific questionnaires. All the variables measuring physical activity improved significantly after 8 weeks of exercise treatment in this group of patients.

At the 6-month assessment, most of the clinical variables that had previously improved after treatment had returned to baseline values. However, almost all the variables measuring physical activity and functional capacity remained significantly better compared with baseline assessment.

At the 1-year followup assessment, none of the clinical variables showed significant improvement with respect to the initial assessment. However, all the variables measuring physical activity remained significantly better than at the initial assessment (Figure 1). There were no differences in the need for analgesic rescue between the posttreatment and 1-year followup assessments (2.4 $\pm$ 2.6 days/week versus 2.9 $\pm$ 2.6 days/week; P = not significant).

CBT group. In this group we also found significant differences in some clinical variables after treatment (Table 2). Some items of the FIQ, including stiffness and the total score, showed a significant improvement at the posttreatment assessment. Patients in this group increased the utilization of strategies, such as relaxation, to cope with pain. As in the PE group, there were no statistical differences in anxiety, depression, and self-efficacy scales measured by specific questionnaires. In this group of patients, only physical activity of vertebral column showed moderate improvement after treatment. However, the physical activity of upper and lower extremities, as well as the aerobic exercise capacity, did not show significant changes at the posttreatment assessment.

At the 6-month assessment, all the clinical variables of the FIQ returned to baseline values, although physical function and general health domains of the SF-36 showed a significant improvement at this time. Functional capacity and physical activity at 6 months was equivalent to that at the beginning of the trial.

After 1 year of followup, all the clinical variables were similar to baseline values. Functional capacity and physical activity variables were also similar to the baseline assessment. However, relaxation strategies were still being used by these patients after 1 year of followup. Analgesic drugs consumption was higher at the 1 year followup assessment with respect to the posttreatment evaluation (3.6 $\pm$ 2.5 days/week versus 2.2 $\pm$ 2.8 days/week; $P = 0.014$), but it did not reach statistical significance.

Between-group differences. At the posttreatment assessment, the only item that showed a significant difference between groups was the use of relaxation strategies by the CBT group. At the 1-year followup assessment, no statistical differences were found in any clinical variables or medication consumption between groups.

Although there was a trend toward a better functional capacity and physical activity in the PE group at the 1-year followup assessment, the differences did not reach statistical significance. In the last visit, the amount of exercise the patients were doing was similar between groups: mean $\pm$ SD 2.9 $\pm$ 2.1 days/week in the PE group and 3.3 $\pm$ 2.7 days/week in the CBT group (P = not significant).

DISCUSSION

The results of this study show that the clinical manifestations of FM improve in the short term both with the ap-

Table 1. Questionnaire scores for the PE group (n = 19)*

	Baseline mean ± SD	Posttreatment mean ± SD	6 month mean ± SD	1 year mean ± SD
Tender point score	15.1 ± 1.9	14.3 ± 3.3	13.9 ± 2.8	13.4 ± 3.8
FIQ				
Physical function	1.6 ± 1.7	1.6 ± 1.7	2.0 ± 1.7	1.6 ± 1.8
Feel good	8.6 ± 1.9	5.0 ± 3.7†	7.0 ± 4.2	7.4 ± 3.2
VAS pain	6.8 ± 1.7	5.6 ± 2.6	6.9 ± 2.4	6.6 ± 2.0
VAS fatigue	7.5 ± 1.9	5.6 ± 2.0†	7.1 ± 2.4	6.8 ± 2.1
VAS sleep	8.2 ± 2.0	6.7 ± 2.6	7.5 ± 2.4	7.5 ± 2.6
VAS stiffness	7.6 ± 2.5	6.0 ± 2.8	6.4 ± 3.0	6.7 ± 2.7
VAS anxiety	6.3 ± 3.3	5.1 ± 3.2†	5.8 ± 3.5	5.8 ± 3.2
VAS depression	5.3 ± 3.3	5.0 ± 3.0	5.3 ± 3.2	4.9 ± 3.5
Total score	52.0 ± 11.4	40.8 ± 13.7†	48.0 ± 17.3	47.7 ± 14.1
SF-36				
Physical functioning	47.1 ± 15.0	47.1 ± 19.3	43.9 ± 21.5	41.6 ± 21.7
Physical role	18.4 ± 24.8	32.2 ± 39.4	18.3 ± 33.7	31.0 ± 32.3
Bodily pain	28.5 ± 9.9	39.8 ± 14.8†	32.9 ± 19.6	34.3 ± 24.2
General health	39.0 ± 17.4	39.3 ± 17.0	37.6 ± 21.0	35.7 ± 15.3
Vitality	31.3 ± 17.3	36.2 ± 17.8	32.6 ± 17.9	34.5 ± 16.6
Social functioning	67.1 ± 26.7	73.0 ± 25.8	66.9 ± 26.1	57.2 ± 32.8
Emotional role	64.9 ± 40.8	66.0 ± 42.8	66.0 ± 42.6	58.7 ± 42.1
Mental health	49.9 ± 24.5	59.0 ± 19.7	51.8 ± 23.6	53.8 ± 31.8
Health change	4.0 ± 1.0	—	—	3.9 ± 1.0
Beck Inventory				
Depression	16.8 ± 13.4	16.8 ± 10.2	15.0 ± 11.4	13.6 ± 11.7
Anxiety	22.1 ± 11.8	22.3 ± 11.3	22.1 ± 12.3	20.0 ± 11.2
CPSS				
Pain management	5.4 ± 2.2	4.7 ± 2.2	3.8 ± 2.6	4.0 ± 2.6
Physical function	7.1 ± 1.8	7.0 ± 1.6	6.5 ± 1.7†	6.4 ± 2.2
Symptoms	5.8 ± 2.3	5.6 ± 1.7	5.0 ± 2.1	4.8 ± 2.6
CPCI				
Asking for assistance	2.2 ± 1.4	1.8 ± 1.4	2.4 ± 1.6	1.9 ± 1.1
Guarding	3.4 ± 1.3	3.3 ± 1.3	3.7 ± 1.3	3.6 ± 1.4
Resting	2.9 ± 1.3	2.6 ± 1.4	3.0 ± 1.2	3.4 ± 1.4
Relaxation	1.9 ± 1.4	1.6 ± 1.4	2.2 ± 1.5	1.8 ± 1.5
Task persistence	4.8 ± 1.4	4.5 ± 1.6	4.3 ± 1.1	4.2 ± 1.0
Exercise	2.2 ± 1.7	3.0 ± 1.7†	3.3 ± 1.2	3.3 ± 1.5
Social support	2.2 ± 1.3	2.0 ± 1.6	2.4 ± 1.5	2.0 ± 1.2
Self statements	2.6 ± 1.5	2.7 ± 1.4	2.9 ± 1.3	3.0 ± 1.5
Physical activity				
Upper limbs	19.9 ± 4.5	23.6 ± 4.0†	22.6 ± 4.7†	23.0 ± 4.5†
Lower limbs	22.7 ± 3.8	26.6 ± 3.4†	25.9 ± 4.0	26.5 ± 3.7†
Vertebral column	17.0 ± 3.5	22.0 ± 4.2†	21.0 ± 4.0†	21.0 ± 5.0†
Aerobic exercise capacity	5.4 ± 0.9	9.6 ± 14.8	6.0 ± 1.2†	5.9 ± 1.1

* PE = physical exercise; FIQ = Fibromyalgia Impact Questionnaire; VAS = visual analog scale; SF-36 = Short Form 36; CPSS = Chronic Pain Self-Efficacy Scale; CPCI = Chronic Pain Coping Inventory.
† $P < 0.01$ compared with baseline assessment.

plication of a CBT treatment and with a treatment based on improving the aerobic capacity and physical fitness of these patients. A substantial number of the items of the FIQ, as well as its total score, showed a favorable evolution in both groups after an 8-week treatment period, indicating an improvement of the clinical manifestations, an improvement in their physical capacity, and a smaller impact on the daily life of the patients. These findings are similar to those of other investigators using treatment protocols similar to ours in short-term studies (12–14,16,17).

We also confirmed that pain had been reduced immediately after treatment in some patients. This suggests that the treatments used improved the most important clinical manifestations of FM patients, and not only patients' functional capacity. Usually, pain intensity is one of the symptoms that varies less in clinical trials in FM patients, although there exists an improvement in the rest of the clinical parameters and in functional capacity.

Our results also confirm the capacity of the FIQ to measure changes, as previously proposed (28), which makes this questionnaire one of the most useful instruments in the clinical investigation of patients with FM.

The variables that measure physical fitness and capacity to perform aerobic exercise only improved in those patients of the PE group but not in the CBT group. This shows that the physical training program of our study was

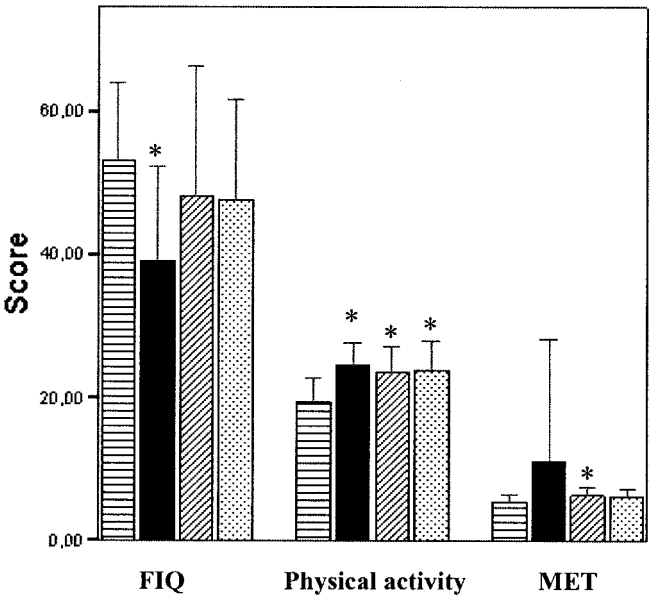

Figure 1. Evolution of clinical manifestations (Fibromyalgia Impact Questionnaire [FIQ] total score) and functional capacity (physical activity and aerobic capacity) in patients with physical exercise treatment at baseline (horizontal striped bar), posttreatment (shaded bar), 6-month followup (hatched bar), and 1-year followup (stippled bar). After cessation of the treatment period, clinical manifestations returned to baseline values but functional capacity remained better than the baseline assessment. Comparisons were done with the baseline assessment. MET = metabolic rate. $^*P < 0.01$.

successful in reaching the aims of improving the functional capacity of these patients. Previously it has been shown that patients with FM, in spite of their poor physical fitness, are able to perform a physical training directed at increasing their muscle strength and their aerobic capacity without any harm to the patient (6,7).

However, the improvement in the functional capacity of patients with FM does not always occur together with an improvement in their clinical manifestations. There are some studies that show an improvement of physical fitness in these patients after the treatment, but without an improvement in their clinical manifestations (11,39). By contrast, there are other studies where the clinical manifestations of FM improved without an improvement of the physical fitness of the patients (12,15).

These data suggest that the improvement of the clinical manifestations of our patients might not be related to the physical training program. More specifically, PE improved physical fitness but not necessarily the clinical manifestations of patients with FM.

Assessing physical fitness in patients with FM is difficult because different questionnaires and physical measures are used by many investigators. To our knowledge, there is no agreement concerning which measures of physical fitness are most suitable in FM patients. The same measure of aerobic exercise capacity used in this study has already been used by other investigators (13,16,38) with positive results measuring changes. The evaluation of physical activity has not been used before in any study, although we daily perform this evaluation on the patients of our Physical Therapy Unit.

Likewise, patients on the CBT program showed improvement in their clinical symptoms immediately after finishing the treatment program. CBT has also shown a capacity to improve the clinical condition of patients with FM through the improvement in the parameters of self efficacy and learning of specific techniques to cope with chronic pain (21). In this group of patients, however, there was not a considerable improvement in the self-efficacy and coping with chronic pain scores. Also, there was no significant difference with the PE group that could explain the improvement in the CBT group through these mechanisms.

Another possible explanation for the clinical improvement in our patients of both groups is the beneficial effect of the intervention. It is well known that belonging to any therapeutic group for a certain period of time may improve the patient's condition. Mood is known to improve with physical exercise (17) and, apparently, the improvement of mood depends on the duration of the treatment program: the longer the treatment, the better results (42).

One of the most relevant findings in our study is that we could check how the beneficial effect of the treatment disappeared as time went by, so that at the end of the study, 1 year from the end of the treatment, there was no clinical variable that showed a significant improvement with respect to the initial evaluation. However, physical fitness in the PE group was better than that found at the initial evaluation (see Figure 1). This finding suggests that the improvement in the physical fitness of patients with FM does not necessarily correlate with an improvement in the clinical manifestations of the disease.

There are few controlled studies in which physical treatment, after producing an initial improvement in the clinical manifestations of FM patients, is assessed in the long-term. Wigers et al (13), after obtaining favorable results of an intervention based on a 12-week exercise program, found that there was neither improvement in the clinical variables nor in the physical fitness of these patients 4 years later. Something similar occurs in the work of Jentoft et al (16), during a 46-week followup period. Our study is, to our knowledge, the first one to show that, in spite of the improvement in the physical fitness of patients with FM 1 year after finishing the treatment program, there was no parallel improvement in the clinical manifestations of FM.

Although the patients in the PE group were in better physical condition after 1 year than in the initial evaluation, the beneficial affect was not caused by the initial exercise treatment program. If patients had not kept doing the exercises learned during the program, the beneficial effect would have disappeared. We, therefore, wonder about the benefits of exercises in this group of patients, given the fact that there was no improvement in the clinical manifestations of the disease. There are many alternative explanations.

In the first place, the loss of physical fitness is progressive in the natural history of FM and is related to the time of evolution of the disease (5). Although the patients do not improve in their clinical manifestations, they are aware that PE gives them a higher functional capacity for daily living activities, avoiding new problems with the clinical manifestations of FM.

Table 2. Questionnaire scores for the CBT group (n = 21)*

	Baseline mean ± SD	Posttreatment mean ± SD	6 month mean ± SD	1 year mean ± SD
Tender points score	15.5 ± 2.0	14.9 ± 3.4	14.1 ± 2.9	14.7 ± 3.2
FIQ				
Physical function	1.3 ± 1.6	1.7 ± 1.9	2.0 ± 2.4	2.0 ± 2.0
Feel good	8.7 ± 1.9	7.7 ± 3.0	7.6 ± 3.0	7.7 ± 2.8
VAS pain	7.3 ± 2.3	6.0 ± 2.5	5.9 ± 2.6	6.3 ± 2.3
VAS fatigue	7.6 ± 2.5	6.3 ± 3.0	6.4 ± 2.8	6.5 ± 2.4
VAS sleep	7.8 ± 2.6	6.3 ± 3.2	7.3 ± 2.5	7.0 ± 2.6
VAS stiffness	7.7 ± 2.7	5.6 ± 3.0†	6.9 ± 2.6	6.9 ± 2.7
VAS anxiety	6.4 ± 3.4	6.5 ± 3.0	6.0 ± 3.1	6.0 ± 3.0
VAS depression	5.2 ± 3.0	4.1 ± 2.8	5.2 ± 3.5	5.4 ± 3.4
Total score	52.0 ± 12.0	44.3 ± 14.5†	47.4 ± 15.4	47.8 ± 14.7
SF-36				
Physical functioning	41.9 ± 22.3	49.3 ± 20.6	52.2 ± 18.4†	38.9 ± 24.0
Physical role	16.7 ± 26.6	20.2 ± 30.2	22.4 ± 35.2	26.1 ± 30.3
Bodily pain	23.3 ± 15.7	33.0 ± 19.5	31.4 ± 20.1	33.8 ± 30.7
General health	25.7 ± 14.8	33.0 ± 14.2	35.5 ± 14.7†	39.7 ± 20.58
Vitality	32.1 ± 16.7	35.9 ± 14.0	38.9 ± 18.0	38.4 ± 14.1
Social functioning	55.3 ± 25.8	61.9 ± 22.9	66.4 ± 30.9	60.7 ± 23.0
Emotional role	45.0 ± 46.2	55.5 ± 45.1	68.4 ± 40.8	66.7 ± 41.3
Mental health	43.7 ± 21.8	49.1 ± 12.5	48.9 ± 20.9	56.5 ± 27.4
Health change	4.2 ± 0.7	—	—	3.3 ± 1.2
Beck Inventory				
Depression	19.2 ± 12.0	15.4 ± 8.8	17.1 ± 12.2	13.0 ± 8.0
Anxiety	24.1 ± 12.3	23.3 ± 11.9	25.2 ± 10.0	20.0 ± 9.0
CPSS				
Pain management	5.1 ± 2.6	5.5 ± 2.3	4.8 ± 2.0	5.8 ± 1.0
Physical function	5.9 ± 2.4	6.4 ± 2.0	6.3 ± 2.6	7.4 ± 2.8
Symptoms	5.2 ± 2.5	5.7 ± 2.3	5.9 ± 2.0	5.2 ± 2.0
CPCI				
Asking for assistance	2.3 ± 1.4	2.4 ± 1.1	2.3 ± 1.5	2.0 ± 1.3
Guarding	3.2 ± 1.3	3.4 ± 1.2	3.6 ± 1.4	3.0 ± 1.4
Resting	3.6 ± 1.5	3.5 ± 1.3	3.2 ± 1.6	3.3 ± 1.0
Relaxation	2.2 ± 1.3	3.4 ± 1.7†	3.2 ± 1.7†	2.9 ± 1.3†
Task persistence	4.3 ± 1.0	4.6 ± 1.5	4.8 ± 3.1	3.8 ± 1.6
Exercise	2.7 ± 1.7	3.4 ± 1.8	3.9 ± 1.9	3.4 ± 1.7
Social support	1.8 ± 1.2	1.8 ± 1.1	2.0 ± 1.7	2.4 ± 1.3
Self statements	3.4 ± 1.4	3.0 ± 1.5	3.2 ± 1.7	3.2 ± 1.5
Functional capacity				
Upper limbs	19.9 ± 4.3	20.9 ± 5.0	20.3 ± 5.1	21.8 ± 5.0
Lower limbs	23.3 ± 4.9	24.0 ± 5.4	23.3 ± 5.3	24.3 ± 5.4
Vertebral column	17.0 ± 2.3	19.0 ± 4.6†	18.7 ± 4.3	18.9 ± 4.1
Aerobic exercise capacity	4.9 ± 1.1	4.9 ± 1.2	5.0 ± 1.2	5.0 ± 1.1

* CBT = cognitive-behavioral therapy; FIQ = Fibromyalgia Impact Questionnaire; VAS = visual analog scale; SF-36 = Short Form 36; CPSS = Chronic Pain Self-Efficacy Scale; CPCI = Chronic Pain Coping Inventory.
† $P < 0.01$ compared with baseline assessment.

In the second place, the performance of PE can also be beneficial because PE improves other aspects of the patient's health. For example, low mood (17), depressive symptoms (42), and anxiety (43), which are frequent in patients with FM, are known to improve with PE. In our study, we could not demonstrate these later aspects, as no significant differences were found in the questionnaires used to measure the variables of depression and anxiety after the intervention, and no specific questionnaire was used to assess mood in our patients. In addition, the scores for anxiety or depression in our patients were not excessively high, which indicates a moderate to low intensity of both symptoms. Questionnaires often better measure the changes produced when scores move in the middle ranges.

Quality of life was measured in our study by the self-administered SF-36. The scores obtained were low in almost all dimensions, indicating a poor quality of life, a result similar to that obtained in other studies (25). The SF-36 questionnaire has been developed to measure quality of life in a generic way and there are no data about its responsiveness to perceived clinical changes in patients with FM. Recently, some investigators have shown there were significant differences in some dimensions after 6 months of treatment with combined exercise and CBT therapy (25).

Physical exercise and CBT treatments have previously demonstrated to be superior to controls in improving clinical manifestations in FM patients. Moreover, nonpharma-

cologic treatments are more efficacious than pharmacologic ones (8). In this study, a control group was not included because the main objective was to check the efficacy of these 2 nonpharmacologic treatment modalities.

Studies of long-term interventions are needed to establish correlations between clinical manifestations and physical fitness improvements in FM patients. Exercise should be done on a daily basis to obtain significant improvements. In CBT long-term interventions, a strategy for maintaining treatment gains should be used (20). Combined CBT and exercise interventions should also be explored in long-term interventions.

In summary, we have found short-term improvement in clinical manifestations of patients with FM with both treatment regimens. In the CBT group, contrary to expectations, this improvement was not associated with a significant change in the variables that measure self efficacy. This suggests that these aspects were not related to clinical improvement. In the PE group, an improvement in the variables that measured physical fitness was found after the treatment, and this improvement lasted the duration of the patients' followup. However, the improvement of the clinical manifestations could only be confirmed right after the conclusion of the intervention, but not 1 year after it. This result suggests that improvement in physical fitness is not necessarily associated with improvement in the clinical manifestations of FM.

REFERENCES

1. Yunus MB. Psychological aspects of fibromyalgia syndrome: a component of the dysfunctional spectrum syndrome. Baillieres Clin Rheumatol 1994;9:811–37.
2. Galeotti N, Ghelardini C, Zoppi M, Bene E, Raimondi L, Beneforti E, et al. A reduced functionality of Gi proteins as a possible cause of fibromyalgia. J Rheumatol 2001;28:2298–304.
3. Crofford LJ, Demitrack MA. Evidence that abnormalities of central neurohormonal systems are key to understanding fibromyalgia and chronic fatigue syndrome. Rheum Dis Clin North Am 1996;22:267–84.
4. Arenas Cabrera C, Bautista Lorite J. Estudios neuromusculares en la fibromialgia. Rev Esp Reumatol 2000;27:430–5.
5. Bennett RM, Clark SR, Goldberg L, Nelson D, Bonafede RP, Porter J, et al. Aerobic fitness in patients with fibrositis: a controlled study of respiratory gas exchange and 133 Xenon clearance from exercising muscle. Arthritis Rheum 1989;32:454–60.
6. Klug GA, McAuley E, Clark S. Factors influencing the development and maintenance of aerobic fitness: lessons applicable to the fibrositis syndrome. J Rheumatol 1989;16 Suppl 19:30–9.
7. Rooks DS, Silverman CB, Kantrowitz FG. The effects of progressive strength training and aerobic exercise on muscle strength and cardiovascular fitness in women with fibromyalgia: a pilot study. Arthritis Rheum 2002;47:22–8.
8. Rossy LA, Buckelew S, Dorr N, Hagglund KJ, Thayer JF, McIntosh MJ, et al. A meta-analysis of fibromyalgia treatment interventions. Ann Behav Med 1999;21:180–91.
9. Ledingham J, Doherty S, Doherty M. Primary fibromyalgia syndrome: an outcome study. Br J Rheumatol 1993;32:139–42.
10. Wolfe F, Anderson J, Harkness D, Bennett RM, Caro XJ, Goldenberg DL, et al. Health status and disease severity in fibromyalgia. Arthritis Rheum 1997;40:1571–9.
11. McCain GA, Bell DA, Mai FM, Halliday PD. A controlled study of the effects of a supervised cardiovascular fitness training program on the manifestations of primary fibromyalgia. Arthitis Rheum 1988;31:1135–41.
12. Martin L, Nutting A, Macintosh BR, Edworthy SM, Butterwick D, Cook J. An exercise program in the treatment of fibromyalgia. J Rheumatol 1996;23:1050–3.
13. Wigers SH, Stiles TC, Vogel PA. Effects of aerobic exercise versus stress management treatment in fibromyalgia. Scand J Rheumatol 1996;25:77–86.
14. Meiworm L, Jakob E, Walker UA, Peter HH, Keul J. Patients with fibromyalgia benefit from aerobic endurance exercise. Clin Rheumatol 2000;19:253–7.
15. Meyer BB, Lemley KJ. Utilizing exercise to affect the symptomology of fibromyalgia: a pilot study. Med Sci Sports Exerc 2000;32:1691–7.
16. Jentoft ES, Kvalvik AG, Mengshoel AM. Effects of pool-based and land-based aerobic exercise on women with fibromyalgia/chronic widespread muscle pain. Arthritis Rheum 2001;45:42–7.
17. Gowans SE, de Hueck A, Voss S, Silaj A, Abbey SE, Reynolds WJ. Effect of a randomized, controlled trial of exercise on mood and physical function in individuals with fibromyalgia. Arthritis Rheum 2001;45:519–29.
18. Burckhardt CS, Mannerkorpi K, Hedenberg L, Bjelle A. A randomized, controlled clinical trial of education and physical training for women with fibromyalgia. J Rheumatol 1994;21:714–20.
19. Keefe FJ, Caldwell DS, Queen KT, Gil KM, Martinez S, Crisson JE, et al. Pain coping strategies in osteoarthritis patients. J Consult Clin Psychol 1987;55:208–12.
20. Keefe FJ, Van Horn Y. Cognitive-behavioral treatment of rheumatoid arthritis pain: maintaining treatments gains. Arthritis Care Res 1993;6:213–22.
21. Hadhazy VA, Ezzo J, Creamer P, Berman BM. Mind-body therapy for the treatment of fibromyalgia. J Rheumatol 2000;27:2911–8.
22. Bennett RM, Burckhardt CS, Clark SR, O'Reilly CA, Wiens AN, Campbell SM. Group treatment of fibromyalgia: a 6 month outpatient program. J Rheumatol 1996;23:521–8.
23. Keel PJ, Bodoky C, Gerhard U, Müller W. Comparison of integrated group therapy and group relaxation training for fibromyalgia. Clin J Pain 1998;14:232–8.
24. Gowans SE, de Hueck A, Voss S, Richardson M. A randomized, controlled trial of exercise and education for individuals with fibromyalgia. Arthritis Care Res 1999;12:120–8
25. Mannerkorpi K, Nyberg B, Ahlmén M, Ekdahl C. Pool exercise combined with an education program for patients with fibromyalgia syndrome. a prospective, randomized study. J Rheumatol 2000;27:2473–81.
26. Wolfe F, Smythe HA, Yunus MB, Bennett RM, Bombardier C, Goldenberg DL, et al. The American college of Rheumatology 1990 criteria for the classification of fibromyalgia. Arthritis Rheum 1990;33:160–72.
27. Burckhardt CS, Clark SR, Bennett RM. The Fibromyalgia Impact Questionnaire: development and validation. J Rheumatol 1991;18:728–33.
28. Dunkl PR, Taylor AG, McConnell GG, Alfano AP, Conaway MR. Responsiveness of fibromyalgia clinical trial outcome measures. J Rheumatol 2000;27:2683–91.
29. Ware JE, Sherbourne CD. The MOS-36 item short form health survey (SF-36). Med Care 1992;30:473–83.
30. Alonso J, Prieto L, Antó JM. La versión española del SF-36 Health Survey (Cuestionario de salud SF-36): un instrumento para la medida de los resultados clínicos. Med Clin Barc 1995;104:771–6.
31. Beck AK, Epstein N, Brown G, Steer RA. An inventory for measuring clinical anxiety: psychometrics properties. J Consult Clin Psychol 1988;56:893–7.
32. Beck AT, Ward CH, Mendelson M, Mock J, Erbaugh J. An inventory for measuring depression. Arch Gen Psychiatry 1961;4:561–71.
33. Lorig K, Chastain RL, Ung E, Shoor S, Holman HR. Develop-

ment and evaluation of a scale to measure perceived self-efficacy in people with arthritis. Arthritis Rheum 1989;32: 37–44
34. Anderson KO, Dowds BN, Pelletz RE, Edwards WT, Peeters-Asdourian C. Development and initial validation of a scale to measure self-efficacy beliefs in patients with chronic pain. Pain 1995;63:77–84.
35. Jensen MP, Turner JA, Romano JM, Strom SE. The Chronic Pain Coping Inventory: development and preliminary validation. Pain 1995;60:203–16.
36. Bruce RA. Exercise testing of patients with coronary artery disease. Ann Clin Res 1971;3:323–32.
37. Ainsworth BE, Haskell WL, Leon AS, Jacobs DR, Montoye HJ, Sallis JF, et al. Compendium of physical activities: classification of energy costs of human physical activities. Med Sci Sports Exerc 1993;25:71–80.
38. Santen M, Bolwijn P, Landewé R, Verstappen F, Bakker C, Hidding A, et al. High or low intensity aerobic fitness training in fibromyalgia: does it matter? J Rheumatol 2002;29:582–7.
39. Mengshoel AM, Komnaes HB, Forre O. The effects of 20 weeks of physical fitness training in female patients with fibromyalgia. Clin Exp Rheumatol 1992;10:345–9.
40. Jamison RD. Mastering chronic pain: a professional's guide to behavioral treatment. Sarasota (FL): Professional Resource Press; 1996.
41. Nielson WR, Walker C, McCain GA. Cognitive behavioral treatment of fibromyalgia syndrome: preliminary findings. J Rheumatol 1992;19;98–103.
42. North TC, McCullagh P, Tran VZ. Effect of exercise on depression. Exerc Sport Sci Rev 1990;18:379–415.
43. Petruzzello SJ, Landers DM, Hatfield BD, Kubitz KA, Salazar W. A meta-analysis on the anxiety-reducing effects of acute and chronic exercise: outcomes and mechanisms. Sports Med 1991;11:143–82.